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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,021	09/16/2003	Mary Kay Delmedico	TRM-001	5500

7590 06/23/2006  
Trimeris, Inc.  
3500 Paramount Way  
Morrisville, NC 27560

EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/664,021

Applicant(s)

DELMEDICO ET AL

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**Restriction Requirement**

**35 U.S.C. § 121**

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-52, drawn to HIV-1 gp41 HR1 **peptides**, classified in class 424, subclasses 188.1 and 208.1, and class 530, subclass 324.
- b. Group II, claim(s) 53-79, drawn to a **method of inhibiting** HIV-1 replication by administering an HIV-1 gp41 HR1 peptide, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

*Product and Process of Using*

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case viral transmission can be inhibited by using a materially different product such as a gp41-specific antibody or gp41 peptidomimetic. Moreover, the peptides of interest can be employed in a number of materially different processes such as the generation of immunological reagents or in affinity purification protocols.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

**37 C.F.R. § 1.48(b)**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

**Claim Rejoinder (M.P.E.P. § 821.04)**

Applicants are reminded that a restriction between product and process claims has been set forth *supra*. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include **all** the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or otherwise include **all** the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims **must** meet all criteria for patentability as set forth under 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so will result in a loss of the right to rejoinder.** Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

#### **Correspondence**

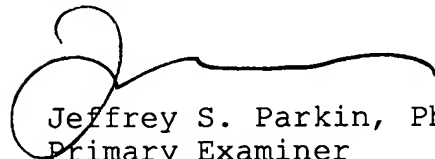
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants: Delmedico, M. K., and J. Dwyer

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

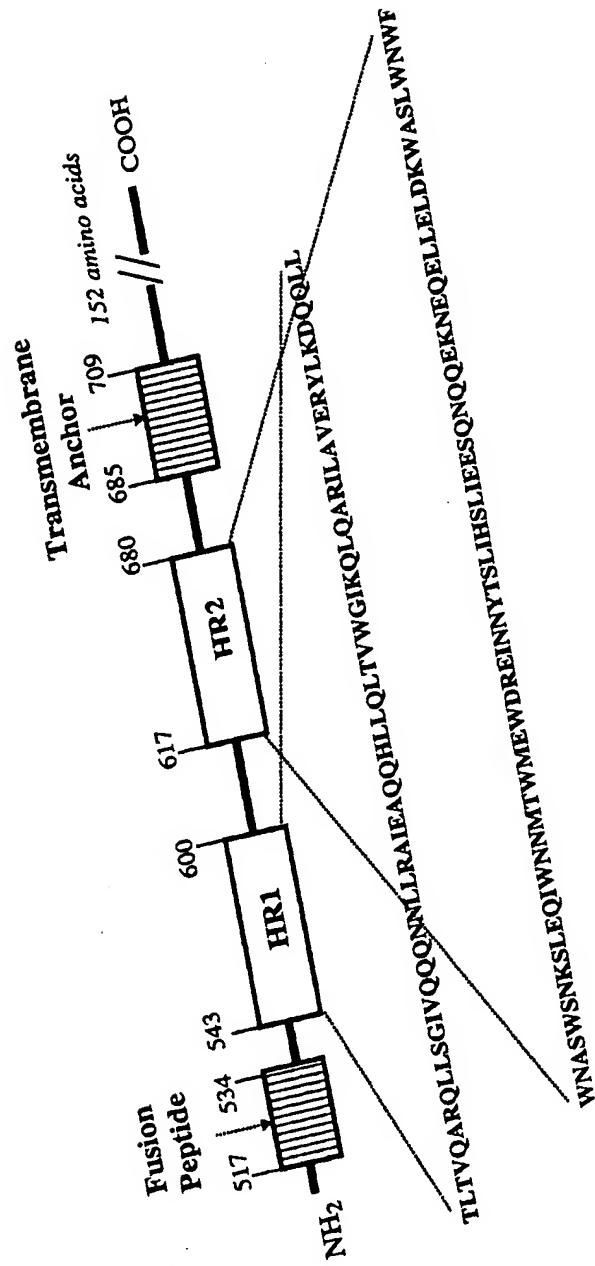
Respectfully,



Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

20 June, 2006

FIG. 1



	10	20	30	40
T-21	-----+-----+-----+-----+-----			
	--NNLLRAIEAQQHLLQLTVWGIKQLQARILAVERYLKDQ			
Gp41bru.pro	QQ.....			Q
Gp41hxb2.PRO	QQ.....			Q
PNL4-3 gp41.PRO	QQ.....			Q
Ug273-A.pro	QQS.....	K.....	L.....	R..Q
Us2-B.pro	QQ.....		V.....	Q
Ug268-C.pro	QQ.....	M.....	T.V..I...	Q..Q
Se365-D.pro	QQ.....			R..Q
CM240-E.pro	QQS.....		V.....	K
Bz126-F.pro	QQ.....		V.....	Q..Q
HH8793-G.pro	QQS.....		V..L...	R..Q
ENV_HV1BN	QQ...M.....	M.E.....	V.....	Q
ENV_HV1C4	QQ.....	K.....		Q
ENV_HV1KB	QQ.....	D.....	V.....	Q
_VCLJH00	QQ.....	K.....		Q
ENV_HV1B8	QQ.....	G.....		Q
ENV_HV1Z8	QQ.....	M.....	V...S...	Q
1	QQT.M.K.....		V.....	Q
2	QQTS.....		V.....	R..Q
3	QQ.D.....	M.....	V..L.G..Q..	Q
4	QQ..M.....	M.....	V.....	R..Q
5	QQS..M.....	L..MV.....	V.....	Q
6	QQS..M.....	M.....	V.....	Q
7	QQX....M....		V..L...R..	Q
8	QQ.D...G.D.P.....		W.....V.....	RG.Q
9	QQ.S..Q.....	RM.....	V.....	Q
10	QQ.D.....	R.....	V..L...R..	Q
11	QQT.M.....		S.....V.....	Q
12	QRS...K.....	QMWR.....	F.....L.....	Q
13	QQ.....	M.....	R..V..I.....	Q
14	QQS.....		PG.....	Q
15	QQ.....		V...K...R..	Q
16	ER.K.R.....	M.....	V...S...	Q
17	HQS.....		V.....	R..Q
18	QQ.D...G.D.P.....		V.....V.....	RG.Q

FIG. 2

	abcd	f	g	abcde	f	g						
QARQLLSGI	VQQQNNLL	R	A	E	AQQHLL	QLTVWGI	KQLQARI	L	AVERYLK	SEQ ID NO:23		
QARQLLSGI	VQQQNNLL	R	A	E	AQQHLL	QATVWGI	KQLQARI	L	AVERYLK	SEQ ID NO:32		
QARQLYSGI	VQQQNNI	L	R	A	E	ATQHAYQAL	VWGVKQL	QARYL	ALERYIK	SEQ ID NO:35		
QIRQLLSGI	VQQQNNLL	R	A	E	A	QHALQA	I	VWGI	KQLQARI	L	AVERYLK	SEQ ID NO:36
QQQNNLL	R	A	E	AQQHLL	QLTVWGI	KQLQARI	L	AVERYLK	KDQ	SEQ ID NO:27		
QQQNNLL	R	A	E	AQQHLL	QLTAWGI	KQLQARI	L	AVERYLK	KDQ	SEQ ID NO:29		
QQQNNLL	R	A	E	AQQHLL	QLTVA	GI	KQLQARI	L	AVERYLK	KDQ	SEQ ID NO:30	

FIG. 3

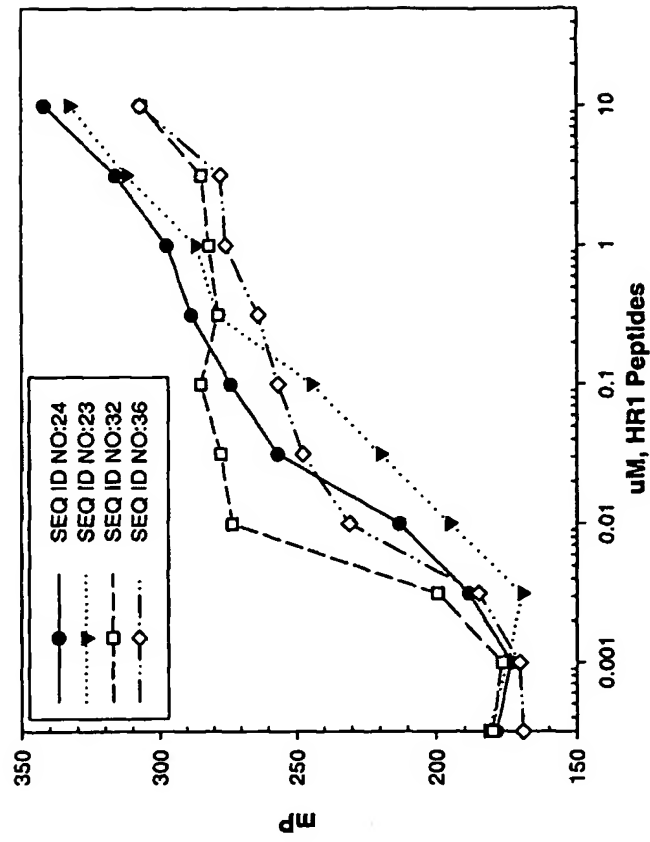


FIG. 4